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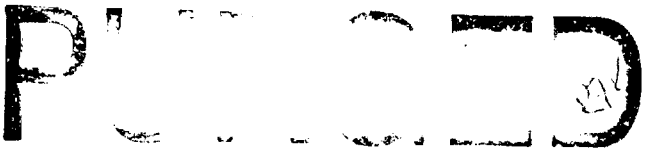
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100



November 18, 1999

xc: HFI-35
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 08

Andrew L. Johnson
President
Andy's Peninsula Fish Market
51 Green Bay Road
Sturgeon Bay, Wisconsin 54235

Dear Mr. Johnson:

The Food and Drug Administration (FDA) conducted an inspection of your seafood manufacturing facilities at the above address on July 28 and 29, 1999, to determine your compliance with the Seafood HACCP and GMP regulations denoted in Title 21, Code of Federal Regulations, Parts 123 and 110, respectively (21 CFR 123 and 110). At the conclusion of this inspection the FDA investigator issued a list of inspectional observations on the form FDA-483 and discussed them with you.

The FDA-483 listed the following violations associated with your smoked fish operation:

> You must implement monitoring procedures at the frequency listed in your HACCP plan in order to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure for checking the internal temperature of the smoked fish, by a visual examination of smokehouse time and temperature charts, at the end of each smoke/cook operation. The critical control point of smoking/cooking is in your HACCP plan for smoked fish.

Please refer to the form FDA-483 dated July 29, 1999, for a more detailed listing of the objectionable findings. The listing of these inspectional observations is not intended to be an all-inclusive listing of the violations at your facility. As the most responsible individual at your facility, you are responsible to ensure your

according to Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) in that they were manufactured and held under conditions whereby they may have been rendered injurious to health. The adulteration of a previously unadulterated food after shipment in interstate commerce and the shipment of an adulterated food in interstate commerce is prohibited by Section 301 of the Act.

Within 15 working days of receipt of this letter please provide a written response detailing the actions you have taken to correct these violations and prevent their recurrence. Also, include a timeline as to the projected completion dates for these corrective actions so we may re-inspect to verify the effectiveness of your corrective action plan.

If you fail to take timely corrective actions, FDA may initiate legal actions against you and/or your products in the form of an injunction or seizure.

Your response and any questions you may have regarding this matter may be directed to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead.

Sincerely,

James A. Rahto
District Director
Minneapolis District

TPN/ccl